

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
16 December 2004 (16.12.2004)

PCT

(10) International Publication Number
WO 2004/108084 A3

(51) International Patent Classification⁷: **A61K 31/485**

(74) Agents: **ELMORE, Carolyn, S. et al.**; Elmore Craig, P.C.,
209 Main Street, Chelmsford, MA 01863 (US).

(21) International Application Number:
PCT/US2004/017496

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(22) International Filing Date: 3 June 2004 (03.06.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/475,863 4 June 2003 (04.06.2003) US

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (*for all designated States except US*): **ALKERMES CONTROLLED THERAPEUTICS, II** [US/US];
88 Sidney Street, Cambridge, MA 02139 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **BRITTAIN, Harry, A.** [US/US]; 10 Charles Road, Milford, NJ 08858 (US). **DICKASON, David, A.** [US/US]; 4739 Vicbarb Lane, Cincinnati, OH 45244 (US). **HOTZ, Joyce** [US/US]; 8219 Pinecone Court, Cincinnati, OH 45249 (US). **LYONS, Shawn, L.** [US/US]; 1113 Alcliff Lane, Cincinnati, OH 45238 (US). **RAMSTACK, Michael, J.** [US/US]; 44 Cortland Circle, Lunenburg, MA 01462 (US). **WRIGHT, Steven, G.** [US/US]; 7012 Juniperview Lane, Madeira, OH 45243 (US).

Published:

— with international search report

(88) Date of publication of the international search report:
17 March 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **POLYMORPHIC FORMS OF NALTREXONE**

(57) Abstract: This invention relates to the discovery of novel polymorphic forms of naltrexone, including solvates, hydrates, anhydrous and other crystalline forms and combinations thereof. These novel forms of naltrexone impart advantages in pharmaceutical formulations incorporating them, including sustained release, or long acting, formulations.



WO 2004/108084 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/17496

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 31/485

US CL : 514/282, 326

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/282, 326

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y --- X	US 6,264,987 B1 (WRIGHT et al .) 24 July 2001 (24.07.2001), col. 8 ,lines 45-47, col. 7, lines 63-65.	47-60 ----- 13-16
X	US 6,277,859 B1 (NAGASE et al) 21 August 2001 (21.08.2001), col. 81, lines 18-20).	17-19
X	US 4,141,897 A (OLOFSON et al.) 27 February 1979 (27.02.1979), col. 20 ,lines 55-57.	26-28
X --- Y	US 6,228,863 B1 (PALERMO et al.) 08 May 2001 (08.05.2001), col. 26, lines 50-55.	1-12, 20-22, and 26-28 ----- 47-60



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

30 October 2004 (30.10.2004)

Date of mailing of the international search report

14 DEC 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Taylor Y. Oh

Telephone No. 571-272-2717

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/17496

Continuation of B. FIELDS SEARCHED Item 3:

West search done : polymorph, naltrexone, toluene, hexane, acetone, ethylacetate, methanol, dichloromethane, ethanol, acetone, dimethylformamide, benzyl alcohol, ethanolate.